

REMARKS

I. Amendments

By this amendment, claims 8 and 12 have been amended and claims 9 and 13 have been cancelled.

The specification has been amended to indicate the priority of the application. In addition, minor typographical errors have also been corrected throughout the specification.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

No change of inventorship is necessitated by this amendment.

II. Discussion of the Rejection under 35 U.S.C. Sec. 112, First Paragraph

Claims 8, 10-12, 14 and 15 have been rejected under 35 U.S.C. Sec. 112, first paragraph as allegedly non-enabled as to the definition of the variable Y.

By this amendment, independent claim 8 has been amended to recite the subject matter of originally filed claim 9 and independent claim 12 has been amended to recite the subject matter of originally filed claim 13. Accordingly, claims 9 and 13 were cancelled. As claims 9 and 13 are not subject to this rejection, Applicants believe that the rejection has been overcome.

Claims 10 and 11 depend upon claim 8 and claims 14 and 15 depend upon claim 12.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

III. Discussion of the Rejection under 35 U.S.C. Sec. 112, Second Paragraph

Claims 8-15 have been rejected under 35 U.S.C. Sec. 112, second paragraph as allegedly vague for several different reasons. Applicants respectfully traverse the rejection.

The Examiner has indicated that several terms and phrases used in independent claims 8 and 12 are vague. Applicants submit that the terms and phrases are fully defined in the specification, such that one skilled in the art would understand the invention. As the test for definiteness according to the MPEP, Sec. 2173.02, is “whether those skilled in the art would understand what is claimed when the claim is read in light of the specification”; Applicants believe that the aspects of the invention as set forth in independent claims 8 and 12 are sufficiently clear.

The Examiner has also indicated that he does not believe that the definitions found in the specification are enough to meet the requirements of Sec. 112, second paragraph; citing two cases as support. It has been indicated by the Examiner that it is not proper to read limitations into the claims from the specification. However, Applicants argue that looking to the specification for the identity of optional substituents is not reading in a new limitation, but rather interpreting a limitation which is already in the claim. The Examiner is respectfully requested to consider the following quote which appears in both of the cases cited.

"Although 'it is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim, ...this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. By 'extraneous,' we mean a limitation read into a claim from the specification wholly apart from any need to interpret... particular words or phrases in the claim" according to *In re Paulson* (30 F3d 1475)

The Examiner has apparently confused interpretation with additional limitation, which the cited case admonishes against. Applicants therefore disagree that it is impermissible to indicate that Sec. 112, second paragraph requirements can be satisfied by reference to definitions in the specification.

To summarize, the claims indicate that the variables can be substituted; and the specification states what the optional substituents are; so there is no impermissible vagueness.

In the following paragraphs, Applicants indicate the portions of the specification which define each term or phrase in contention, for the Examiner's convenience.

Particularly with respect to the use of the phrase "optionally substituted" Applicants note that they have well over 200 issued U.S. patents which include this language in the claims. A few examples are U.S. Patent Nos. 6,723,722; 6,673,761 and 6,498,179. In addition, Supervisory Examiner Shah has participated in the prosecution of nearly a thousand patents which include this language. Some examples include U.S. Patent Nos. 6,737,418 and 6,677,339. Thus Applicants believe that there is ample precedent for their assertion of the definitiveness of their claims in the use of the phrase "optionally substituted".

The location in the specification of the descriptions of each of the terms and phrases which the Examiner has objected to follows.

"optionally substituted acyl group"

This phrase is explained in the specification on page 21, lines 7-10 and page 17, line 20 – page 18, line 13 *inter alia* with respect to Y in claims 8 and 12.

"optionally substituted hydrocarbon group"

This phrase is explained in the specification on page 16, line 20 – page 18, line 13 *inter alia* with respect to R¹, R², R³, R⁴, R⁵, R⁶ and R⁷ in claims 8 and 12.

"optionally substituted acyl group"

This phrase is explained in the specification on page 24, line 20 – page 18, line 13 *inter alia* with respect to R¹ in claims 8 and 12.

"optionally substituted sulfonyl group"

This phrase is explained in the specification on page 24, line 17 -23 *inter alia* with respect to R¹ in claims 8 and 12.

“optionally substituted amino group”

This phrase is explained in the specification on page 19, lines 3-13 *inter alia* with respect to R², R³, R⁴, R⁵, R⁶ and R⁷ in claims 8 and 12.

“optionally substituted hydroxyl group”

This phrase is explained in the specification on page 19, lines 14-18 *inter alia* with respect to R², R³, R⁴, R⁵, R⁶ and R⁷ in claims 8 and 12.

“optionally substituted thiol group”

This phrase is explained in the specification on page 19, lines 19-23 *inter alia* with respect to R², R³, R⁴, R⁵, R⁶ and R⁷ in claims 8 and 12.

“optionally substituted heterocyclic group”

This phrase is explained in the specification on page 21, lines 2-6 *inter alia* with respect to R², R³, R⁴, R⁵, R⁶ and R⁷ in claims 8 and 12.

“heterocyclic”

This term is defined in the specification at page 19, line 24 – page 21, line 1 *inter alia*.

“may form a ring”

The rings formable from the combination of R¹ and R², R¹ and R⁴, R² and R³, R⁴ and R⁵, R² and R⁴ are described in the specification at page 18, lines 14-24 *inter alia*, while rings formable from the combination of R⁶ and R⁷ are described in the specification at page 22, line 19 – page 23, line 6 and page 23, lines 16-20 *inter alia*.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

IV. Discussion of the Rejection under 35 U.S.C. Sec. 102(b) in view of Krastinat

Claims 8, 10-12, 14 and 15 have been rejected under 35 U.S.C. Sec. 102(b) as allegedly anticipated by Krastinat (U.S. Patent No. 4,243,678). Applicants respectfully traverse this rejection

By this amendment, independent claim 8 has been amended to recite the subject matter of originally filed claim 9 and independent claim 12 has been amended to recite the subject matter of originally filed claim 13. Accordingly, claims 9 and 13 were cancelled. As claims 9 and 13 are not subject to this rejection, Applicants believe that the rejection has been overcome.

Claims 10 and 11 depend upon claim 8 and claims 14 and 15 depend upon claim 12. Applicants submit that the more specific dependent claims are also not anticipated by the cited reference.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(b) rejection in view of Krastinat.

V. Discussion of the Rejection under 35 U.S.C. Sec. 102(b) in view of Lehman

Claims 8, 10-12, 14 and 15 have been rejected under 35 U.S.C. Sec. 102(b) as allegedly anticipated by Lehman (Canadian Patent No. 1013960). Applicants respectfully traverse this rejection

By this amendment, independent claim 8 has been amended to recite the subject matter of originally filed claim 9 and independent claim 12 has been amended to recite the subject matter of originally filed claim 13. Accordingly, claims 9 and 13 were cancelled. As claims 9 and 13 are not subject to this rejection, Applicants believe that the rejection has been overcome.

Claims 10 and 11 depend upon claim 8 and claims 14 and 15 depend upon claim 12. Applicants submit that the more specific dependent claims are also not anticipated by the cited reference.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(b) rejection in view of Lehman.

VI. Discussion of the Rejection under 35 U.S.C. Sec. 102(b) in view of Krastinat *et al.*

Claims 8, 10-12, 14 and 15 have been rejected under 35 U.S.C. Sec. 102(b) as allegedly anticipated by Krastinat *et al.* (GB 2 024 813 A). Applicants respectfully traverse this rejection

By this amendment, independent claim 8 has been amended to recite the subject matter of originally filed claim 9 and independent claim 12 has been amended to recite the subject matter of originally filed claim 13. Accordingly, claims 9 and 13 were cancelled. As claims 9 and 13 are not subject to this rejection, Applicants believe that the rejection has been overcome.

Claims 10 and 11 depend upon claim 8 and claims 14 and 15 depend upon claim 12. Applicants submit that the more specific dependent claims are also not anticipated by the cited reference.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(b) rejection in view of Krastinat *et al.*

VII. Discussion of the Rejection under 35 U.S.C. Sec. 102(b) in view of Berry *et al.*

Claims 8, 10-12, 14 and 15 have been rejected under 35 U.S.C. Sec. 102(b) as allegedly anticipated by Berry *et al.* (J. Chem. Soc. 1969 article). Applicants respectfully traverse this rejection

By this amendment, independent claim 8 has been amended to recite the subject matter of originally filed claim 9 and independent claim 12 has been amended to recite the subject matter of originally filed claim 13. Accordingly, claims 9 and 13 were cancelled. As claims 9 and 13 are not subject to this rejection, Applicants believe that the rejection has been overcome.

Claims 10 and 11 depend upon claim 8 and claims 14 and 15 depend upon claim 12. Applicants submit that the more specific dependent claims are also not anticipated by the cited reference.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 102(b) rejection in view of Berry *et al.*

VIII. Discussion of the Rejection under 35 U.S.C. Sec. 103(a) in view of Englert *et al.*

Claims 8, 10-12, 14 and 15 have been rejected under 35 U.S.C. Sec. 103(a) as allegedly obvious in view of Englert *et al.* (EP 0 237 918). Applicants respectfully traverse this rejection

By this amendment, independent claim 8 has been amended to recite the subject matter of originally filed claim 9 and independent claim 12 has been amended to recite the subject matter of originally filed claim 13. Accordingly, claims 9 and 13 were cancelled. As claims 9 and 13 are not subject to this rejection, Applicants believe that the rejection has been overcome.

Claims 10 and 11 depend upon claim 8 and claims 14 and 15 depend upon claim 12. Applicants submit that the more specific dependent claims are also not obvious in view of the cited reference.

Therefore Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 103(a) rejection in view of Englert *et al.*

IX. Conclusion

Reconsideration of the claims and allowance is requested. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

Dated: July 27, 2004

Elaine M Ramesh

(847) 383-3391
(847) 383-3372

Elaine M. Ramesh, Ph.D., Reg. No. 43,032
Mark Chao, Ph.D., Reg. No. 37,293

Attorney for Applicants
Customer No. 23,115

Takeda Pharmaceuticals North America, Inc.
Intellectual Property Department
Suite 500, 475 Half Day Road
Lincolnshire, IL 60069 USA